JUL - 5 2000

K001117

R & D MEDICAL PRODUCTS, INC.

510(k) SUMMARY

(Sheet 1 of 2)

Submitter's name: James Tran
Contact Person: James Tran
Tel. Number: 562-274-0361

Email Address: jtran_00@yahoo.com

Date of preparation: January 10, 2000

Name of the device: **COMFORT STIM Electrode**
Stimulator, Nerve, Transcutanuous For Pain Relief Electrode

Legally market device(s):
K881343 (Sentry Medical Product)
K962910 (Uni-Patch - Medical Supplies)
T2000W series (Vermont Medical)
TEQ and MTAN Electrodes (BNE – Medical Supply)
Superior Silver (Uni-Patch)

Description of the Device: **COMFORT STIM** Electrode is a self-adhesive, disposable device commonly referred to in the industry as a TENS electrode. It features with the backing materials that provides durable, flexible and useful for different surface areas. This backing material will be laminated to a carbon vinyl coated with silver/silver chloride ink for minimum electrical current transmitting. The adhesive hydrogel used with **COMFORT STIM** electrodes is the ProCam RG-63B gel of which passed the required skin sensitivity, cytotoxicity, and biocompatibility testing criteria as specified in the Biocompatibility Guidance for Medical Devices (ProCam Gel: FDA Device Master File # 131). The same conductive gel has been used on TENS and NMES/FES Electrodes (K962910) marketed by Uni-Patch.

Intented Use of the Device: **COMFORT STIM** Electrodes are intended for use as a disposable, self-adhesive, and conductive interface between the patients skin and the TENS unit and is ordered by a certified physician.

Technological Characteristic: The **COMFORT STIM** Electrode is equivalent to the predicate device. It is physically and technically similar to those currently marketed.

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Vmail/Pager 714 273-0074 Fax 949 472-9347 Email rdmedical@aol.com

K00117

R & D MEDICAL PRODUCTS, INC.

510(k) SUMMARY

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Uni-Patch, Vermont Medical, and TC Medical are companies which offer products like **R&D COMFORT STIM**. Other medical suppliers such as BNE Medical Supply, American Health Supplies, American IMEX, and Master Medical also cary the same product as **R&D COMFORT STIM** in design, function, and intended use.

Performance Summary: There are no published performance standards for TENS or Muscle Stimulation Electrodes. R&D Medical Products evaluates the safety and effectiveness of the device by testing the impedance levels of its product and comparing with TENS Pain Management Center. The result is also determined to be substantially equivalent to others that have been previously 510(k) approved.

Manufacturing: COMFORT STIM will be manufactured according to the product specifications and under good manufacturing practices that ensure the device is safe and effective for its intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2000

Mr. James Tran
R & D Medical Products, Inc.
20492 Crescent Bay Drive
Building 106
Lake Forest, California 92630

Re: K001117
Trade Name: Comfort Stim Electrodes
Regulatory Class: II
Product Code: GXY
Dated: January 2, 2000
Received: April 6, 2000

Dear Mr. Tran:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Diane R. Lochner.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K001117

DEVICE NAME: COMFORT STIM ELECTRODES

INDICATIONS FOR USE:

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COMFORT STIM is a TENS Electrode which is intended ~~for use as~~ the disposable, adhesive conductive interface between the patient's skin and the TENS Stimulator. These electrodes will include the precaution statement: ~~U.S.A. Federal Law restricts~~ this device to sale by or on the order of a physician.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Dianne R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001117